

PART 67—NATIONAL CENTER FOR HEALTH SERVICES RESEARCH GRANTS

Subpart A—Grants for Health Services Research, Evaluation, and Demonstration Projects

Subpart A—Grants for Health Services, Research, Evaluation, and Demonstration Projects

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§67.10 Purpose and scope.

The regulations of this subpart are applicable to the award through the National Center for Health Services Research of grants under section 305(b) of the Public Health Service Act (42 U.S.C. 242c(b)) to support identified health services research, evaluation, or demonstration projects to investigate:

- (a) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;
- (b) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and
- (c) The design, construction, utilization, organization, and cost of facilities and equipment.

§67.11 Definitions.

As used in this subpart:

- (a) *Act* means the Public Health Service Act.
- (b) *Budget period* means the interval of time (usually 12 months) into which the project has been divided for budgetary and reporting purposes and for which the Government has made a financial commitment to fund a particular project.
- (c) *Direct costs* means the costs that can be identified specifically with a particular cost objective, such as compensation of employees for the time and effort devoted specifically to the approved project, and the costs of materials acquired, consumed or expended specifically for the purpose of the approved project.
- (d) *Grantee* means the public or non-profit entity or individual that receives a grant under section 305(b) and this subpart for a health services research, evaluation or demonstration project and assumes legal and financial responsibility for the funds awarded and for the performance of the grant supported activity.

(e) *National Center for Health Services Research* means that unit of the Department of Health and Human Services established by section 305(a) of the Act.

(f) *Nonprofit* as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any shareholder or individual.

(g) *Project period* means the total period of time for which support for a project has been approved as specified in the grant award document. Such approval does not commit or obligate the Federal Government to any additional, supplemental or continuation support beyond the current budget period.

(h) *Principal investigator* means a single individual, designated in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project.

(i) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(j) *Peer review group* means a panel of experts who are neither officers nor employees, other than by reason of their appointment, of the United States qualified by training and experience in particular scientific and technical fields to give expert advice, in accordance with the provisions of this subpart, on the scientific and technical merit of grant applications.

§ 67.12 Eligibility.

(a) *Eligible applicants.* Any public or private nonprofit entity and any individual is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 305(b) of the Act and this subpart may be made to eligible applicants for the purpose of assisting in meeting the costs of health services research, evaluation, or demonstration projects as described in § 67.10; *Provided*, That no grant may be made under this subpart for any health services research, evaluation, or demonstration project for which a grant under another provision of the Act (other than section 304) may be made.

§ 67.13 Application.

(a) An application for a grant under this subpart shall be submitted at such time and in such form and manner as the Secretary may prescribe, and shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the act, the regulations of this subpart and any additional terms or conditions of any grant awarded.

(b) In addition to such other information as the Secretary may require, an application under this subpart must contain the following:

(1) A description of the problem in the area of health services that the project will address;

(2) A description of the hypotheses that will be tested or the specific objectives that will be served by the project as they relate to the general problem area;

(3) A description of the manner in which the project will be organized and managed;

(4) A specification of the data that will be collected or used in the project;

(5) A description of the analytic procedures that will be employed in the project;

(6) The names and qualifications of the principal investigator and principal members of the staff that will be assigned to the project and their roles;

(7) A description of the facilities and resources that will be available to the applicant, if any; and

(8) A complete and detailed budget and justification for the amount of grant funds being requested.

§ 67.14 Evaluation of applications.

(a) *Projects with direct costs over the project period in excess of \$35,000.* (1) All applications for grant support under this subpart for a project with estimated direct costs over the project period in excess of \$35,000 will be submitted by the Secretary for review to a peer review group whose members will be selected based upon their training and experience in relevant scientific and technical fields taking into account among other factors:

(i) The level of formal education (e.g., M.A., Ph. D., M.D.) completed by the individual;

(ii) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigators, assistant) in which the individual has done so, and the quality of such research;

(iii) The extent of the professional recognition received by the individual as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services; and

(iv) The need of the peer review group to include within its membership experts from various areas of specialization within relevant scientific and technical fields.

(2) In carrying out a review under this paragraph the peer review group will take into account where appropriate:

(i) The significance and originality from a scientific or technical standpoint of the goals of the project;

(ii) The adequacy of the methodology proposed to carry out the project;

(iii) The availability of data or the proposed plan to collect data required in the analyses;

(iv) The adequacy and appropriateness of the plan for organizing and carrying out the project;

(v) The qualifications of the principal investigator and proposed staff;

(vi) The reasonableness of the proposed budget in relation to the proposed project;

(vii) The adequacy of the facilities and resources available to the grantee; and

(viii) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

(3) The peer review group to which an application has been submitted pursuant to this paragraph shall make a written report to the Secretary on each application so submitted which shall contain the following parts:

(i) The first part shall consist of a factual summary of the proposed project, including a description of its purpose, scientific approach, location, total budget and manpower requirements.

(ii) The second part shall address the scientific and technical merit of the proposed project and shall consist of a critique of the proposed project with regard to the factors described in §67.14(a)(2). This portion of the report shall include a set of recommendations to the Secretary with respect to the disposition of the application based upon its scientific and technical merit. The peer review panel may recommend that the Secretary approve, disapprove or defer a decision on the application in order to obtain further information. Where the peer review panel recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application. Where the peer review panel recommends approval, it shall also provide its recommendation regarding the appropriate project period and level of support for the proposed project.

(iii) The third part of the report shall describe the peer review panel's review of the importance of the problem that is to be addressed by the proposed project and its potential impact.

(b) *Project with direct costs over the project period of \$35,000 or less.* (1) Applications for grant support under this subpart for a project with estimated direct costs over the project period of \$35,000 or less (hereinafter sometimes referred to as "small grants") will be submitted by the Secretary for review to members of the staff of the National Center for Health Services Research and where desirable to assess the scientific merit of an application to at least two outside experts who are neither officers nor employees of the United States selected by the Director of the National Center for Health Services Research on the basis of their training and experience in particular scientific and technical fields, their knowledge of health services research and the application of research findings, and their special knowledge of the problem being addressed in the specific proposal.

(2) In carrying out a review under this paragraph, the reviewers will, take into account where appropriate:

(i) The significance and originality from a scientific or technical standpoint of the goals of the project;

(ii) The adequacy of the methodology proposed to carry out the project;

(iii) The availability of data or the proposed plan to collect data required in the analyses;

(iv) The adequacy and appropriateness of the plan for organizing and carrying out the project;

(v) The qualifications of the principal investigator and proposed staff;

(vi) The reasonableness of the proposed budget in relation to the project;

(vii) The adequacy of the facilities and resources available to the grantee; and

(viii) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

(3) Each reviewer to which an application has been submitted pursuant to this paragraph shall make a written report to the Secretary on each application so submitted. Each report shall summarize the reviewer's findings and provide recommendations with regard to approval, disapproval, or deferral of the application in order to obtain additional information.

§ 67.15 Disposition of applications.

On the basis of the Secretary's evaluation of the application as provided in § 67.16, the Secretary shall either (a) approve, (b) defer for a later decision, or (c) disapprove any application for grant assistance under this subpart: Disapproval of an application shall not preclude its reconsideration if the application is resubmitted in the same or a revised version at a later date.

§ 67.16 Grant award.

(a) *General.* (1) Within the limits of funds available for such purpose and subject to the limitation of section 308(c) of the Act, the Secretary may award grants to those applicants whose approved projects will in his judgment best promote the purposes of section 305(b) of the Act and the regulations of this subpart, taking into consideration:

(i) Recommendations made pursuant to § 67.14.

(ii) The appropriateness of the budget.

(iii) The extent to which the research proposal and the fiscal plan provide assurance that effective use will be made of grant funds.

(iv) The business management capability of the applicant.

(v) The competence and skill of the staff, especially the senior personnel, in light of the scope of the project.

(vi) The probable usefulness of the project results for dealing with national health care problems, policies, and programs.

(vii) The relative priority of the proposed project in light of the established priorities of the National Center for Health Services Research.

(2) In making any grant award the Secretary may add additional conditions to or require specific modifications in the project as proposed in the application including a different level of grant support from that requested in the application. In such cases the Secretary will obtain either the written agreement of the applicant to proceed on such basis prior to making any grant award or such condition or modification will appear on the Notice of Grant Award.

(3) All grant awards shall be in writing. The Notice of Grant Award shall set forth the amount of funds awarded for the conduct of the approved project during the first budget period and the amount of annual support recommended for the remainder of the project period.

(4) The project for any grant under this subpart shall be specified in the Notice of Grant Award and shall begin no later than 9 months following the date of such award. In no case will a project be approved for a project period exceeding 5 years. Where the Secretary determines on the basis of a request by the grantee prior to the completion of the currently active grant that additional time is needed to permit the use of funds previously awarded but not expended, the approved project may be extended for a period of time not to exceed 12 months except that in no case may the project period exceed 5 years and 6 months. No additional support may be awarded for any portion of a project period in excess of 5 years.

(5) Neither the approval of any application nor the awarding of any grant

shall commit or obligate the Federal Government in any way to make any additional, supplemental, continuation or other awards with respect to the project or any part of the project. For continuation support, grantees must make separate application annually and at such times and in such form as the Secretary may prescribe.

(b) *Determination of grant amount.* (1) The amount of any grant shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for the indirect costs, if any, which will be calculated by the Secretary either:

(i) On the basis of the estimate of the actual indirect costs reasonable related to the project; or

(ii) On the basis of a percentage of all or a designated portion of the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs such as fringe benefit rates subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(2) For particular categories of small grants, such as dissertation research support, the Secretary may establish a limit on direct costs that is less than \$35,000 for the project period. Such limit will be announced in advance of the deadline for receipt of applications for such grants.

(c) *Supplemental awards.* The Secretary may make supplemental awards during the course of any budget period of an approved project where the Secretary finds on the basis of the applicant's written request and such progress and accounting reports as the Secretary may require that the amount of the award initially approved was less than the amount necessary to carry out the approved project activities for that period, or that a supplemental award to fund incremental activities not initially approved for the

period would substantially further the objectives of the project. The Secretary may also make a supplemental award where in his judgment such an award is necessary for the preparation of data in suitable form for transmittal in accordance with §67.25. In cases where the award of any supplemental grant for a project exceeding \$35,000 in direct costs would result in supplemental awards (excluding any supplemental award for preparation of data in suitable form for transmittal in accordance with §67.25) during the project period in the aggregate exceeding twenty percent (20 percent) of the approved direct costs of the project, the Secretary will obtain the views of the peer review group which first evaluated the initial application prior to making any such award. The peer review group shall submit a written report to the Secretary which describes the current status of the project, the basis for the request and the potential consequences of any request where the recommendation is to disapprove. In the case of small grants, the Secretary will not approve any supplemental grant award during the project period (excluding any supplemental award for preparation of data in suitable form for transmittal in accordance with §67.25) which will in the aggregate exceed ten percent (10 percent) of the direct costs of the project.

(d) *Noncompeting continuation awards.* Where a grantee has filed an application for continuation support and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period of any previously approved project where the Secretary finds on the basis of such progress and accounting reports as may be required and after considering any recommendations made pursuant to this paragraph, that the project activities during the current budget period justify continued support of the project for an additional budget period. Each project with a project period in excess of 2 years and with direct costs over the project period in excess of \$35,000 will be reviewed during the second budget period and during each subsequent budget period (except for the last budget period of the

project period) by at least two members of the same peer group which reviewed the proposal in accordance with §67.14. Such group shall review the application for continuation support and make recommendations to the Secretary concerning the disposition of such application based upon its evaluation of:

- (1) The progress of the project in meeting project objectives,
- (2) The appropriateness of the management of the project and allocation of resources within the project,
- (3) The adequacy and appropriateness of the plan for the carrying out of the project during the budget period in light of the accomplishments during previous budget periods, and
- (4) The reasonableness of the proposed budget for the subsequent budget period where the Secretary determines to continue support, the amount of grant award shall be determined in accordance with paragraph (b) of this section. Where the Secretary determines not to continue a project for an additional budget period, the grantee will be notified in writing before the end of the current budget period.

§67.17 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

- (a) The project shall be carried out in accordance with the approved application.
- (b) The principal investigator shall be responsible for the conduct of the project unless replaced by another individual found by the Secretary to be qualified to carry out such responsibilities. Where the principal investigator becomes unable to function in such capacity, the Secretary shall be notified as soon as possible.

§67.18 Grant payments.

The Secretary will from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he determines such payments are necessary to promote prompt initiation and advancement of the approved project. The amounts oth-

erwise payable to any grantee shall be reduced by:

- (a) Amounts equal to the fair market value of any equipment or supplies furnished to such grantee at their request by the Secretary for the purpose of conducting the approved project; and
- (b) Amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the government in connection with such approved project, if such officer or employee was assigned or detailed by the Secretary at the request of the grantee to perform such services.

§67.19 Use of project funds.

(a) Any funds granted pursuant to this subpart shall be expended by the grantee solely for carrying out the approved project in accordance with the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles, prescribed in subpart Q of 45 CFR part 74.

(b) The grantee may not in whole or in part delegate or transfer this responsibility for the use of such funds to any other person, or other legal entity, without the specific prior written approval of the Secretary.

(c) Prior approval by the Secretary is required whenever there is to be a significant change in the scope or nature of the approved project.

§67.20 Termination.

The termination of any grant under this subpart will be governed by the relevant provisions of subpart M of 45 CFR part 74 and the terms and conditions of the grant award. Where a grantee unilaterally terminates a portion of a grant, the Secretary may terminate such grant in whole where he determines that the remaining portion of the grant will not accomplish the purposes for which the grant was made.

§67.21 Nondiscrimination.

Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

- (a) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulation, 45 CFR part 80

(prohibiting discrimination in Federally assisted programs on the ground of race, color, or national origin).

(b) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 974) and its implementing regulation, 45 CFR part 84 (prohibiting discrimination in Federally assisted programs on the basis of handicap).

(c) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR part 86 (prohibiting discrimination on the basis of sex in Federally assisted education programs).

(d) Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

§67.22 Human subjects and animal welfare.

(a) No award may be made under this subpart unless the applicant has complied with 45 CFR part 46 and other applicable requirements pertaining to the protection of human subjects.

(b) No award may be made under this subpart unless the applicant has complied with chapter 1-43 of the Department of Health and Human Services Grants Administration Manual and any other requirements concerning animal welfare.

§67.23 Publications and copyright.

(a) *Copyright.* Except as may otherwise be provided under the terms and conditions of the award, the grantee is free to copyright any book or other copyrightable materials developed under the grant, subject to a royalty-free, nonexclusive and irrevocable license of the Department to reproduce, publish, alter, or otherwise use, and to authorize others to use the work for Government purposes. In any case in which a copyright has been obtained, the Secretary shall be so notified.

(b) *Publications.* Any reports, papers, statistics, or other materials developed from work supported in whole or in part by an award made under this subpart shall be submitted to the Secretary. The Secretary may make such materials available and disseminate the material on as broad a basis as

practicable and in such form as to make such materials understandable.

§67.24 Confidentiality.

No information obtained by a grantee in the course of its health services research, evaluation, or demonstration activities may be used for any purpose other than the purpose for which it was supplied (which shall include the disclosure of such information to the Secretary for carrying out his responsibilities under the Health Services Research, Health Statistics, and Medical Libraries Act of 1974, Pub. L. 93-353), unless authorized under regulations of the Secretary. Further, such information may not be published or released in other than statistical form if the person who supplied the information or who is described in it is identifiable unless such person has signed a written consent on such forms and in such manner as the Secretary may prescribe.

§67.25 Control of data.

Except as otherwise provided on the terms and conditions of the award and subject to the confidentiality requirements of §67.24, all data collected or assembled for the purposes of carrying out health services research, demonstration, or evaluation projects supported under this subpart shall be made available to the Secretary upon request.

§67.26 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this subpart: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall

be computed on the basis of such pre-determined fixed-percentage rates applied to the total or a selected element of the reimbursable direct costs incurred.

(b) *Accounting for royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under grant shall be accounted for as follows:

(1) Royalties received during the period of grant support as a result of copyrights or patents shall be retained by the grantee and in accordance with the terms and conditions of the grant, be disposed of under either, or a combination of the following options:

(i) Used by the grantee for any purposes that further the objectives of the legislation under which the grant was made.

(ii) Deducted from the total project costs for the purpose of determining the net costs on which the Federal share of costs will be based.

(2) Royalties received after the completion or termination of grant support shall be disposed of as follows:

(i) Patent royalties shall be governed by agreements between the Assistant Secretary for Health, Department of Health and Human Services, and the grantee pursuant to the Department's patent regulations (45 CFR parts 6 and 8).

(ii) Copyright royalties may be retained by the grantee, unless the terms and conditions of the grant or a specific agreement negotiated between the Secretary and the grantee provide otherwise, except State or local government grantees which receive royalties in excess of \$200 a year shall return the Federal share of the excess amount (computed by applying the percentage of Federal participation in the cost of the grant supported project to the excess amount) to the Federal Government, unless specific agreement provides otherwise.

(c) *Grant closeout*—(1) *Date of final accounting.* In addition to such other special and periodic accounting as the Secretary may require, a grantee shall render with respect to each approved project a full account, as provided

herein, as of the termination of grant support which shall be at the end of the project period or the date of any termination of grant support pursuant to the applicable provisions of subpart M of 45 CFR part 74 and the terms and conditions of the grant award.

(2) *Final settlement.* There shall be payable to the United States as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraph (a) of this section and (ii) any other amounts due pursuant to the applicable provisions of 45 CFR part 74 and the terms and conditions of the grant award. Such total sum shall constitute a debt owed by the grantee to the United States and shall be recovered from the grantee or its successors or assignees by set-off or other action as provided by law.

§ 67.27 Applicability of 45 CFR part 74.

The provision of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to States and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to other grantee organizations under this subpart:

45 CFR PART 74

Subpart:

- A—General.
- B—Cash Depositories.
- C—Bonding and Insurance.
- D—Retention and Custodial Requirements for Records.
- F—Grant-Related Income.
- G—Matching and Cost Sharing.
- K—Grant Payment Requirements.
- L—Budget Revision Procedures.
- M—Grant Closeout, Suspension, and Termination.
- O—Property.
- Q—Cost Principles.

§ 67.28 Additional conditions.

The Secretary may, with respect to any grant awarded under this subpart, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project or the conservation of grant funds.

Subpart B—Grants for Health Services Research Centers

AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); sec. 305(d), as amended, 88 Stat. 364; (42 U.S.C. 242c(d)).

SOURCE: 41 FR 5226, Feb. 4, 1976, unless otherwise noted.

§ 67.101 Purpose and scope.

(a) The regulations of this subpart are applicable to the award of grants under section 305(d) of the Public Health Service Act, as amended, to assist in meeting the costs of planning, establishing and operating multidisciplinary Health Services Research Centers by providing support for both permanent staff composed of experts from different disciplines and the administrative costs of carrying out multidisciplinary health services research, evaluations and demonstrations respecting:

(1) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;

(2) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and

(3) The design, construction, utilization, and cost of facilities and equipment.

(b) Additional support awarded under this subpart, for National Special Emphasis Centers is intended to support staff, research, demonstration, and evaluation projects, training programs, and administrative costs for activities appropriate to the particular area of special emphasis.

§ 67.102 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act, as amended.

(b) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) *Nonprofit* as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any shareholder or individual.

(d) *Project period* means the total period of time for which support for a project has been approved as specified in the grant award document. Such approval does not commit or obligate the Federal government to any additional, supplemental or continuation support beyond the current budget period.

(e) *Budget period* means the interval of time (usually 12 months) into which the project has been divided for budgetary and reporting purposes and for which the Government has made a financial commitment to fund a particular project.

(f) *Center* means a Health Services Research Center supported under this subpart.

(g) *National Special Emphasis Center* mean a Center which directs a substantial portion of its efforts in research training, technical assistance, and other appropriate activities to a particular aspect of health care delivery specified by the Secretary and requiring a particular kind of scientific expertise. Such Centers shall include:

(1) A Health Care Technology Center, which shall focus on all forms of technology, including computers and electronic devices, and its applications in health care delivery;

(2) A Health Care Management Center, which shall focus on the improvement of administration and organization in the health field, the training and retraining of administrators of health care enterprises, and the development of leaders, planners and policy analysts in the health field; and

(3) Such other Centers as the Secretary shall deem appropriate, provided that formal notification of the competition for a grant award and designation as a National Special Emphasis Center under this subpart shall be made at least ninety (90) days prior to the closing date for filing applications for Center grants.

(h) *State* means one of the 50 States, the District of Columbia, Puerto Rico, Guam, Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(i) *Grantee* means the public or nonprofit private entity that receives a grant under section 305(d) of the Act and this subpart and assumes legal and financial responsibility for the funds

awarded and for the performance of the grant supported activity.

(j) *Director* means a single individual, designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific, technical, and administrative direction of the Center.

§ 67.103 Eligibility.

Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart; *Provided*, That no entity is eligible for assistance for more than one Center at any one time.

§ 67.104 Application.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such manner as the Secretary may prescribe.¹

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the Act, the regulations of this subpart and the terms and conditions of any grant award.

(c) In addition to such other pertinent information as the Secretary may require, an application for a grant under this subpart shall contain the following:

(1) A description of the manner in which the applicant intends to plan and establish a Center, including a timetable for making the proposed Center operational;

(2) A description of the staff of the proposed Center, including their qualifications, academic training, responsibilities and functions;

(3) A description of the manner in which the staff will be organized and supervised to carry out the proposed activities of the Center;

(4) A description of the applicant's plan for providing at the Center educational opportunities to students, health professionals and other appropriate individuals;

(5) A description of the applicant's plan for sharing the knowledge and expertise of the Center's staff by providing technical assistance to appropriate organizations and individuals and through other forms of public and community services;

(6) A description of the applicant's plan for disseminating the Center's research findings to appropriate forums;

(7) A description of the need of the region in which the proposed Center will be located for a Center and a description of the areas of research which the applicant expects the Center to address by virtue of particular problems and characteristics of the local health care delivery system;

(8) A description of the organizational structure of the applicant and the nature of any relationship with and access to health care delivery systems in which research activities can be undertaken and research findings tested;

(9) A description of the procedures by which research projects will be selected, including the methodology to be utilized in ensuring that such projects will be selected on the basis of (i) the regional or national importance of the problem to be addressed, (ii) the unique potential for definitive research on a problem, and (iii) opportunities for local application of the research findings;

(10) A budget which allocates the total support both by type of expenditure and by the activities identified in paragraphs (c) (1), (4), (5), (6), and (9) of this section;

(11) A description of the resources which the applicant plans to make available to the proposed Center;

(12) A description of the proposed Center's relationships with other academic institutions and research organizations with regard to the impact of such relationships on the quality and scope of the Center's research and the responsiveness of its project selection to local, regional and national priorities; and

(13) Assurances satisfactory to the Secretary that the Center will meet the operational requirements of § 67.107 when it becomes operational.

(d) In addition to the material specified in paragraph (c) of this section, an

¹Applications and instructions are available from the Director, Review and Advisory Services, National Center for Health Services Research, Health Resources Administration, 5600 Fishers Lane, Rockville, MD 20852, Room 15-35.

application for a grant with a designation as a National Special Emphasis Center shall also contain the following:

(1) A description of the areas of research which the applicant expects the Center to address by virtue of the particular problems and characteristics of the field of special emphasis;

(2) A description of the nature of any relationships with and access to health care delivery systems that would enhance the ability to carry out research, evaluations, and demonstrations in management, technology, or other areas of special emphasis;

(3) A description of the procedures by which special emphasis projects will be selected including the methodology to be utilized in ensuring that such projects will be selected on the basis of national importance of the problem being addressed and the unique potential for definitive research on a problem;

(4) A description of the resources which the applicant plans to make available to enhance the special emphasis activities;

(5) A description including a budget, of the proposed Center's plan for disseminating its research findings to groups and individuals particularly concerned with the area of special emphasis; and

(6) Assurances satisfactory to the Secretary that it will meet the additional operational requirements of § 67.107 when it becomes operational.

§ 67.105 Evaluation and disposition of applications.

(a) *Evaluation.* (1) All applications for a grant under this subpart will be submitted by the Secretary for review to a panel of experts who are neither officers or employees of the United States and who possess qualifications necessary to evaluate both the applicant's proposed method of planning, establishing and operating a Center and the potential of the proposed Center to make a valuable scientific contribution (hereinafter referred to as the review panel).

(2) The review panel to which an application has been submitted pursuant to paragraph (a)(1) of this section shall make a written report to the Secretary on each application so submitted. Each

report shall consist of the following parts:

(i) The first part shall consist of a factual summary of the proposed Center, including a synopsis of the information required under § 67.104(c). If the applicant is applying for an award as a National Special Emphasis Center a factual summary of the information provided in accordance with § 67.104(d) shall also be submitted.

(ii) The second part shall address the scientific and technical merit of the application and shall consist of a critique of the proposal and an assessment of the adequacy of the applicant's plan and available resources for meeting the requirements of § 67.107.

(iii) The third part, where appropriate, shall address the scientific and technical merit of the application for an additional award for a National Special Emphasis Center. This part of the report shall consist of a critique of the proposal and an assessment of the adequacy of the applicant's plan and available resources for meeting the additional requirements of § 67.107.

(iv) The fourth part shall describe the panel's assessment of the relevance of the proposed program to regional or national health care issues.

(v) The fifth part shall consist of a set of recommendations to the Secretary with respect to the disposition of the application:

(A) The panel may recommend that the Secretary approve, disapprove, or defer a decision in order to gather further information on an application for support as a Health Services Research Center. If the panel recommends approval, it shall also provide its recommendation regarding an appropriate project period and an appropriate level of support. If it recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application.

(B) The panel may also recommend that the Secretary approve, disapprove, or defer a decision in order to gather further information on an application for additional support as a National Special Emphasis Center. If the panel recommends approval, it shall also provide its recommendation regarding an

appropriate project period and an appropriate level of support. If it recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application.

(b) *Disposition.* On the basis of the Secretary's evaluation of the application and taking into consideration any recommendations made pursuant to paragraph (a) of this section, the Secretary shall either (1) approve, (2) defer for a later decision or (3) disapprove any application for grant assistance under this subpart. Such disapproval of an application shall not preclude its reconsideration if the application is re-submitted in the same or a revised version at a later date.

§67.106 Grant awards.

(a) *General.* (1) Within the limits of funds available for such purpose, the Secretary may award a grant to those applicants whose approved proposed Centers will in his judgment best promote the purposes of section 305(d) of the Act and this subpart, taking into consideration:

(i) Recommendations made pursuant to §67.105.

(ii) The appropriateness of the proposed budget and the extent to which the fiscal plan provides assurance that effective use would be made of grant funds.

(iii) The capability of the applicant as demonstrated by organizational and institutional arrangements to successfully operate the proposed Center.

(iv) The qualifications, achievements, and commitment of the senior personnel.

(v) The strength and scientific integrity of the general program and approach of the proposed Center.

(vi) The nature of the sponsoring institution's commitment to the proposed Center and the relative importance it ascribes to the endeavor.

(vii) The past success and future potential of the proposed Center's personnel in receiving permanent and project related support from other sources.

(viii) The extent to which a proposed Center's planning process incorporates the concerns of pertinent constituents and reflects an awareness of significant research problems in health services.

(ix) The strength of the relationship the proposed Center has developed with components of a local health care system in which specific projects will be conducted and research findings tested.

(x) The integration of disciplinary interests within the proposed Center and the coordination of the research program with training and educational efforts.

However, no grant may be awarded which will result in more than twenty per centum (20%) of all Centers supported under this subpart being located in any one HHS region, except that this restriction shall not operate to proscribe awarding at least two grants under this subpart to institutions located in any single HHS region; *Provided*, That to the extent feasible, the Secretary will make such grants as will result in at least six Centers being operational in each fiscal year.

(2) In making any grant award the Secretary may add additional conditions to or require specific modifications in the Center as proposed in the application including a different level of grant support from that requested in the application. In such cases the Secretary will obtain either the written agreement of the applicant to proceed on such basis prior to making any grant award or such condition or modification will appear on the grant award notice.

(3) All grant awards shall be in writing. The Notice of Grant Awarded shall set forth the amount of funds awarded for the conduct of the Center during the first budget period and the amount of support recommended for the remainder of the project period.

(4) The project period for any grant under this subpart shall be specified in the Notice of Grant Awarded and shall begin no later than nine months following the date of such award. In no case may a project period exceed five years; *Provided*, That the approved project period may be extended for a period not to exceed six months beyond five years where the Secretary determines on the basis of a request by the grantee prior to the termination of the currently active grant that such additional time is needed to permit the use

of funds previously awarded but not expended. No additional support may be awarded for this period.

(5) Neither the approval of any application nor the awarding of any grant shall commit or obligate the Federal Government in any way to make any additional, supplemental, continuation or other awards with respect to the Center or any part of the Center. For continuation support, grantees must make separate application annually and at such times and in such form as the Secretary may prescribe.

(b) *Determination of grant amount.* The amount of any grant shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the Center plus an additional amount for the indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all or a designated portion of the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs.

Such award may include an estimated provisional amount for indirect costs or for designated direct costs such as fringe benefit rates subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) *Supplemental awards.* The Secretary may make supplemental awards during the course of any budget period of an approved Center where the Secretary finds on the basis of the applicant's written request and such progress and accounting reports as the Secretary may require that the amount of the award initially approved was less than the amount necessary to carry out the approved Center activities for that period. The Secretary may also make a supplemental award where in his judgment such an award is necessary for the preparation of data in suitable form for transmittal in ac-

cordance with § 67.113. However, where the making of any supplemental award would result, in any budget period, in supplemental awards exceeding twenty per centum (20%) of the original award for direct Center costs in that budget period, the Secretary will prior to making such award obtain the recommendation of the review panel which evaluated the Center's initial application. The review panel shall submit a written report to the Secretary which describes the current status of the Center, the basis for the request, the panels recommendation concerning the request and the potential consequences of any request that is disapproved.

(d) *Non-competing continuation awards.* Where a grantee has filed an application for continuation support and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period where the Secretary finds on the basis of such progress and accounting reports as may be required that the Center's activities during the current budget period justify continued support of the project for an additional budget period. Where the Secretary determines to continue support, the amount of grant award shall be determined in accordance with paragraph (b) of this section. Where the Secretary determines not to continue a project for an additional budget period, the grantee will be notified in writing before the end of the current budget period. In addition, where he determines such support is necessary, the Secretary may provide financial support for the orderly phase-out of the supported activity.

§ 67.107 Operational requirements.

(a) Any Center supported under this subpart shall:

(1) Have a full-time Director who possesses a demonstrated capacity for sustained productivity and leadership in health services research, demonstrations, and evaluations. The Director shall oversee the research program and the general operation of the Center and shall to the extent practicable directly participate in research activities.

Where the Director of a Center becomes unable to function in such capacity, the grantee shall so inform the Secretary as quickly as possible. Within five (5) days, the grantee shall designate an Interim Director and inform the Secretary of the name of such individual. Within ninety (90) days, the grantee shall nominate an Acting Director who, if approved by the Secretary, shall serve in that capacity until the end of the budget period. The failure to obtain Secretarial approval of a new Director in the prescribed period of time shall result in immediate suspension of the grant;

(2) Have such additional full-time professional staff representing various disciplines relevant to health services research as necessary to plan, establish and operate the proposed Center and to carry out or administer research projects undertaken with the Center. The number and expertise of the staff shall be determined by the size of the proposed Center, the availability to it of staff resources other than its own immediate staff, and the nature and scope of the problems which its research will address;

(3) Be located within an established academic or research institution with available resources appropriate to the proposed activities to be conducted by the Center;

(4) Have written agreements with clinical settings which provide for settings appropriate for the initiation and evaluation of experiments in health services research;

(5) Select problems in health services for research, demonstrations and evaluations respecting:

(i) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;

(ii) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and

(iii) The design, construction, utilization, organization, and cost of facilities and equipment on the basis of (A) their regional or national importance, (B) the unique potential for definitive research on the problem, (C) the opportunities for local application of the research findings;

(6) Provide educational opportunities, through formal mechanisms, for university students, health professionals or other appropriate individuals;

(7) Provide for the dissemination of its research findings, subject to the requirements for confidentiality as set forth in section 308(d) of the Act and §67.112;

(8) Provide, through a formal mechanism, for consultations and technical assistance to concerned individuals and groups of the geographical area in which the Center will be located.

(b) National Special Emphasis Centers shall, in addition to the requirements of paragraph (a) of this section:

(1) Provide for the dissemination of its research findings on a national scale to groups and individuals particularly concerned with the area of special inquiry;

(2) Select problems in its area of special emphasis for research, demonstration and evaluation on the basis of the national importance of the problem being addressed and the unique potential for definitive research;

(3) Provide, through a formal mechanism, for consultations and technical assistance appropriate to its area of special expertise to concerned individuals and groups on a national scale; and

(4) Employ all of the resources made available to the Center by virtue of its National Special Emphasis designation in planning, conducting and monitoring research, training, technical assistance, and other appropriate activities solely in its area of special emphasis.

§67.108 Grant payments.

The Secretary shall from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he determines such payments are necessary to promote prompt initiation and advancement of the approved Center. The amounts otherwise payable to any grantee shall be reduced by:

(a) Amounts equal to the fair market value of any equipment or supplies furnished to such grantee at their request

by the Secretary for the purpose of planning, establishing or operating the Center; and

(b) Amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the government in connection with such Center, if such officer or employee was assigned or detailed by the Secretary at the request of the grantee to perform such services.

§ 67.109 Use of project funds.

(a) Any funds granted pursuant to this subpart shall be expended by the grantee solely for planning, establishing or operating the approved Center in accordance with the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

(b) The grantee may not in whole or in part delegate or transfer this responsibility for the use of such funds to any other person, or other legal entity, without the specific prior written approval of the Secretary.

(c) Prior approval by the Secretary is required whenever there is to be a significant change in the scope or nature of the Center's approved activities.

§ 67.110 Nondiscrimination.

(a) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall on account of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing title VI which applies to grants made under this subpart have been issued by the Secretary with the approval of the President (45 CFR part 80).

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped person in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be

subjected to discrimination under any program or activity receiving Federal financial assistance.

(c) Grant funds used for remodeling, alteration or repairs shall be subject to the conditions that the grantee shall comply with the requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

§ 67.111 Publications and copyright.

(a) *Copyright.* Except as may otherwise be provided under the terms and conditions of the award, the grantee is free to copyright any book or other copyrightable materials developed under the grant, subject to a royalty-free, nonexclusive and irrevocable license of the Department to reproduce, publish, alter or otherwise use, and to authorize others to use the work for Government purposes. In any case in which a copyright has been obtained, the Secretary shall be so notified.

(b) *Publications.* Any reports, papers, statistics, or other materials developed from work supported in whole or in part by an award made under this subpart shall be submitted to the Secretary. The Secretary may make such materials available and disseminate the material on as broad a basis as practicable and in such form as to make such materials understandable.

§ 67.112 Confidentiality.

No information obtained by a Center in the course of its health services research activities directly supported under this subpart may be used for any purpose other than the purpose for which it was supplied (which shall include the disclosure of such information to the Secretary for carrying out his responsibilities under the Health Services Research, Health Statistics, and Medical Libraries Act of 1974 (Pub. L. 93-353), unless authorized under regulations of the Secretary. Further, such information may not be published or released in other than statistical form if the person who supplied the information or who is described in it is identifiable unless such person has signed a written consent on such forms and in such manner as the Secretary

may prescribe. For purposes of this section and §67.113, the term “directly supported”, as it relates to health services research, demonstration, or evaluation projects, means discrete, identifiable projects supported under this subpart and not to solely the provision of administrative and staff support for the Center.

§67.113 Control of data.

Except as otherwise provided in the terms and conditions of the award and subject to the confidentiality requirements of §67.112, all data collected or assembled for the purposes of carrying out health services research, demonstration, or evaluation projects directly supported under this subpart (as that term is defined in §67.112) shall be made available to the Secretary upon request.

§67.114 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this subpart; *Provided however,* That when the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under such grant, shall be accounted for as follows:

(1) *State and local governments.* When the grantee is a State or local government as defined in 45 CFR 74.3, royal-

ties shall be accounted for as provided in 45 CFR 74.44.

(2) *Grantees other than State and local governments.* Where the grantee is not a State or local government as so defined, royalties shall be accounted for as follows:

(i) Patent royalties, whether received during or after the project period, shall be governed by agreements between the Assistant Secretary for Health, Department of Health and Human Services, and the grantee, pursuant to the Department's patent regulations (45 CFR parts 6 and 8).

(ii) Copyright royalties, whether received during or after the grant period, shall first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials; and any royalties in excess of the costs of publishing or producing such materials shall be distributed in accordance with chapter 1-420 or the Department of Health and Human Services Grants Administration Manual.²

(c) *Grant closeout—(1) Date of final accounting.* In addition to such other special and periodic accounting as the Secretary may require, a grantee shall render with respect to each Center a full account, as provided herein, as of the termination of grant support which shall be (i) the end of the project period, or (ii) the date of any termination of grant support pursuant to subpart M of 45 CFR part 74.

(2) *Final settlement.* There shall be payable to the United States as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraph (a) of this section and (ii) any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74. Such total sum shall constitute a debt owed by the grantee to the United States and shall be recovered from the grantee or its successors or assignees

²The Department of Health and Human Services Grants Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

§ 67.115

by set-off or other action as provided by law.

§ 67.115 Reports.

Each grant awarded under this subpart shall be subject to the condition that the grantee shall file written notification with the Secretary of each research, demonstration or evaluation project undertaken by the Center on the date that such project is initiated. Such notification shall include:

- (a) A description of the project, including the hypotheses to be tested or the objectives to be pursued;
- (b) The names of the principal investigators and the principal staff members that will be assigned to the project; and
- (c) A budget, including an identification of the source of funds.

§ 67.116 Human subjects.

No award may be made under this Subpart unless the applicant has complied with 45 CFR part 46 and other applicable requirements pertaining to the protection of human subjects.

§ 67.117 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative re-

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quirements and cost principles, shall apply to all grants under this subpart to States and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to other grantee organizations under this subpart:

45 CFR PART 74

Subpart:

- A General.
- B Cash Depositories.
- C Bonding and Insurance.
- D Retention and Custodial Requirements for Records.
- F Grant-Related Income.
- G Matching and Cost Sharing.
- K Grant Payment Requirements.
- L Budget Revision Procedures.
- M Grant Closeout, Suspension, and Termination.
- O Property.
- Q Cost Principles.

§ 67.118 Additional conditions.

The Secretary may, with respect to any grant awarded under this subpart, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved Center or the conservation of grant funds.